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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/097,023	06/12/1998	JILL MCFADDEN	290252021800	2472
28075	7590	05/28/2004	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/097,023

Applicant(s)

MCFADDEN ET AL.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58, 59 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 is/are rejected.
- 7) ☒ Claim(s) 51 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/10/04 has been entered.

### ***Drawings***

The amendment filed 5/10/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: fig. 5 shows new matter of a braid (210) that is spaced free from the inner and outer liners. Fig. 6 shows new matter of a coil (216) that is established in contact with an inner liner, but free from the outer liner.

Applicants are required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

Claims 1-15, 17-22, 24-42, 44-56, 58, 59, and 61-63 are objected to because the claims do not clearly recite what Applicant views as their invention. Applicants point out that the phrase "generally not radially expandable" is described in the specification at pg. 8, lines 17-20. Since Applicants are relying on this description to clarify the claims, the claims would be clearer

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and confusion avoided if Applicants recited this description in the claims. If Applicants define “generally not radially expandable” as described in the specification, they are requested to include the phrase “does not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit member.” If this description does not fully describe “generally not radially expandable” then Applicants are requested to point to descriptions in the specification that describe and clarify the meaning of “generally not radially expandable.”

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53, 54, 55, 56, 58, and 59 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 05-220225 in view of SAMSON (U. S. Patent No. 5,702,373). JP 05-220225 shows a knitted reinforcing metal member 35 with an inner liner and outer cover. Samson is relied upon for description of the JP 05-220225 document.

Claims 1-5, 13, 14, 18, 19, 20, 24-27, 31-33, 40, 41, 45, 46, 47, 50, 53-56, 58, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by LEONI (U. S. Patent No. 5,772,681). Leoni describes a catheter having a knitted reinforcing member of nitinol between an inner liner and outer cover that is generally not expandable in the section adjacent to the balloon section (1:13-15, 2:48-3:20, 4:10-20, 5:28-29).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK (US Patent No. 4,637,396) in view of COX (US Patent No. 5,257,974). Cook discloses a catheter section having an elongate knit tubular multifilament member 23 made of interlocking up and down loops having an inner liner 22 and outer cover 24 and radiopaque markers. (See figs. 2, 4; col. 1, lines 21-25, 44-51; col. 2, line 29 - col. 3, line 9). Cook discloses that the catheter section is made so that it only expands to a predetermined diameter. Cook does not describe what predetermined diameters are selected. Cox teaches a multi-layered catheter that is made for predetermined expansion of less than 2.7% so the catheter could be used safely in intravascular procedures. (col. 3, lines 27-36; col. 25, lines 28-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cox in the catheter of Cook in order to protect a patient during intravascular procedures.

Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK and COX as applied to claims 1, 13, 31, 38, and 40 above, and further in view of LEONI. Cook and Cox disclose the claimed invention except for using nitinol as the knitted layer. Leoni teaches using nitinol as the knitted layer to restrict expansion

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as a reinforcement layer (5:26-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Leoni in the device of Cook and Cox in order to make use of the well known properties of NiTi for use in a patient's vascular. See col. 5, lines 14-27. The use of stainless steel and platinum in medical devices to make use of their notoriously well-known properties would be obvious to the ordinary artisan and Applicants have not stated that they have achieved any unexpected results different from these materials well-known properties and usage.

Claims 6-12, 15, 21, 28-30, 34-39, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI and further in view of ANDERSEN et al. (U. S. Patent No. 5,674, 276). JP 05-220225 or Leoni disclose the claimed invention except for using multifilaments with first and second materials of a metal and a polymer. Andersen teaches using multifilaments with first and second materials of a metal and a polymer to give desired characteristics to the knitted material for making tubular medical devices where the tube has a knitted member between an inner liner and outer cover (1:50 - 2:46, 4:32-43, 6:5-43, 8:2-7). The tubular device, disclosed by Anderson, is made of a knitted member that generally does not expand, but rather experiences plastic deformation to increase its dimensions (3:19-21). Andersen also teaches the use of radiopaque material to aid in visualizing the device internally. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Andersen in the invention of JP 05-220225 or Leoni in order to tailor the tubular device with different properties to achieve different functions (6:54-58). The use of stainless steel and platinum in medical devices to make use of their notoriously well-known properties

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would be obvious to the ordinary artisan and Applicants have not stated that they have achieved any unexpected results different from these materials well-known properties and usage.

Claims 17, 22, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI as applied to claims 54, 1, and 58 respectively above, and further in view of JANG et al. (U. S. Patent No. 4,898,591). JP 05-220225 or LEONI disclose the claimed invention except for the materials of construction of the inner and outer liner and cover respectively. Jang teaches the use of polyethylene as an inner liner and outer cover of a reinforced catheter to provide desired mechanical properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of JP 05-220225 or Leoni in order to achieve the desired flexibility, torsion and column rigidity for the catheter.

Claims 17, 22, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK and COX as applied to claims 1, 54, and 58 respectively above, and further in view of JANG et al. (U. S. Patent No. 4,898,591). Cook and Cox disclose the claimed invention except for polyethylene inner and outer liner and cover. Jang teaches the use of polyethylene as an inner liner and outer cover of a reinforced catheter to provide desired mechanical properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of Cook and Cox in order to achieve the desired flexibility, torsion and column rigidity for the catheter.

***Allowable Subject Matter***

Claims 51 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Comments concerning Applicants' remarks***

Applicants' arguments regarding reading "knitted" to mean "woven or braided" are not convincing. The prior states that the intermediate layer is knitted.

Applicants' arguments concerning what is meant by "generally non-radially expandable" are not clear. If Applicant requires terms from the specification to clarify this phrase then the terms from the specification should be recited in the claims to prevent confusion and promote clarity.

Applicants state that Leoni does not show a knit member generally not radially expandable. The examiner disagrees and refers to claim 9 where Leoni establishes the middle section to have an expandable section (i.e., the expandable part of the balloon) and a non-expandable section.

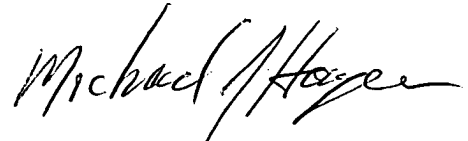
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
26 May 2004

A handwritten signature in black ink, appearing to read "Michael J. Hayes", written in a cursive style.

**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**